

### REMARKS/ARGUMENTS

In response to the Final Office Action of May 29, 2007, Applicant provides the following comments and arguments.

This response is being submitted on or before July 30, 2007 making this a timely response (as July 29<sup>th</sup> was a Sunday). Therefore, this response meets the requirements for expedited review. Consequently, expedited review is respectfully requested.

Claims 20, 21 and 22 have been amended to more distinctly claim the invention. The term "uncrosslinked" has been added. Support for the amendment can be found throughout the specification.

No new matter has been added.

Amendments of the claims should not be considered an acquiescence to the pending rejections. The amendments have been provided in order to expedite the prosecution of the application. Applicants reserve the right to present such unamended claim in this or a continuation application.

#### Rejection of Claims 22 through 24 and 29 through 34 Under 37 C.F.R. § 112

Claims 22-24 and 29-34 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 22 has been amended to provide antecedent basis for the phrase "hydrogel core".

Reconsideration and withdrawal of the rejection is respectfully requested.

#### Rejection of Claims 22 and 23 Under 37 C.F.R. § 102

Claims 22 and 23 are rejected under 35 U.S.C. § 102(b) as being anticipated by Park et al. (U.S. Patent No. 6,271,278)(hereinafter "Park"). Applicants respectfully traverse the rejection for at least the following reason.

The present invention pertains to a prosthetic spinal disc nucleus comprising a hydrogel core selected from the group consisting of uncrosslinked poly(acrylamides), poly(N-vinyl-2-pyrrolidones), polyacrylates, poly (vinyl alcohols), poly(ethylene oxides), polyacrylonitriles, and acrylamide/acrylonitrile block co-polymers having cations incorporated into the hydrogel core, such that the swelling rate of the hydrogel core is increased relative to a hydrogel core devoid of such cations.

Park teaches *crosslinked* hydrogels. All of Park's teachings focus on crosslinking of various ethylenically unsaturated monomers to form a matrix that contains a "fast water-absorbing material", noted as a disintegrant.

The present invention *does not include a crosslinked hydrogel nor a disintegrant*. In contrast the present invention pertains to a hydrogel core selected from the group consisting of poly(acrylamides), poly(N-vinyl-2-pyrrolidones), polyacrylates, poly (vinyl alcohols), poly(ethylene oxides), polyacrylonitriles, and acrylamide/acrylonitrile block co-polymers having cations incorporated into the hydrogel matrix.

Park fails to teach or suggest that the swelling rate of any hydrogel core is increased relative to a hydrogel core devoid of cations.

Therefore, Park does not teach or suggest the subject matter as presently claimed.

Applicants respectfully request reconsideration and withdrawal of the pending rejection.

Rejection of Claims 20, 21, 24 and 29 through 34 Under 35 U.S.C. § 103

Claims 20 and 21 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Park .

Claims 24 and 29-34 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Park as applied to claims 22 above, and further in view of the following.

Claims 25-28 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Park et al. as set forth in the above rejection of claims 20 and 21 and further in view of the following.

The present application is drawn to an improved prosthetic spinal disc nucleus having a hydrogel core sized for implantation into a nucleus cavity and configured to hydrate from a dehydrated state to a hydrated state at a natural swelling rate. The hydrogel core is adapted to support opposing vertebrae in the hydrated state, wherein the hydrogel core is selected from the group consisting of *uncrosslinked* poly(acrylamides), poly(N-vinyl-2-pyrrolidones), polyacrylates, poly (vinyl alcohols), poly(ethylene oxides), polyacrylonitriles, and acrylamide/acrylonitrile block co-polymers to hydrate at an elevated swelling rate that is at least 125% greater than the natural swelling rate.

The present application is also drawn to an improved prosthetic spinal disc nucleus having a hydrogel core sized for implantation into a nucleus cavity and configured to hydrate from a dehydrated state to a natural equilibrium swelling level adapted to support opposing vertebrae. The hydrogel core is selected from the group consisting of *uncrosslinked* poly(acrylamides), poly(N-vinyl-2-pyrrolidones), polyacrylates, poly (vinyl alcohols), poly(ethylene oxides), polyacrylonitriles, and acrylamide/acrylonitrile block co-polymers such that the device hydrates to an elevated equilibrium swelling level that is at least 110% greater than the natural equilibrium swelling level.

The arguments presented above for Park are reiterated here in their entirety.

Park fails to teach or suggest, provide any reason to a person having ordinary skill in the art that an *uncrosslinked* hydrogel would be suitable for a prosthetic spinal disc nucleus. Crosslinked hydrogels are different than uncrosslinked hydrogels. For example, crosslinked hydrogels may not swell due to constraints in the molecular network.

The Office Action notes that Park teaches dehydration of superporous hydrogels decreases swelling time.

This is interesting but this simply shows that the polymer can be dehydrated and then rehydrated back to its initial state. It does not teach or suggest, provide any motivation or a reason for a person having ordinary skill in the art to consider that the *crosslinked* hydrogel could ever achieve as swelling that is at least 110% greater, let alone 125% than the natural

equilibrium swelling level. Again, it is more likely than not that the crosslinked material could not swell beyond its initial state due to the crosslinks.

Park fails to teach or suggest, provide any motivation or an expectation of success to a person having ordinary skill in the art that the uncrosslinked hydrogel suitable for a prosthetic spinal disc nucleus would be selected from poly(acrylamides), poly(N-vinyl-2-pyrrolidones), polyacrylates, poly (vinyl alcohols), poly(ethylene oxides), polyacrylonitriles, and acrylamide/acrylonitrile block co-polymers.

Park fails to teach or suggest, provide any motivation nor an expectation of success to a person having ordinary skill in the art that the uncrosslinked hydrogel suitable for a prosthetic spinal disc nucleus would hydrate to an elevated equilibrium swelling level that is at least 110% greater than the natural swelling rate, let alone 125% greater than the natural swelling rate.

The Office Action further states that Park discloses all of the limitations of the present invention except the specific types of cations.

Applicants respectfully disagree. Again, as stated above, Park provides a crosslinked hydrogel. This is very different than the uncrosslinked systems of the present invention. Inclusion of cations in a crosslinked hydrogel may in fact cause the crosslinked network to not swell as much as when the hydrogel is devoid of such cations. It is simply unknown what would happen to such a crosslinked hydrogen network as disclosed by Park, when cations would be included and if the hydrogel would swell as much or to a lesser or greater extent to that of the crosslinked hydrogel without such cations. One of ordinary skill in the art are not provided a teaching, a suggestion or any reason why cations should be included in a *crosslinked* hydrogel, let alone an *uncrosslinked* hydrogel, such as that of the present invention.

The Office Action also states that Park teaches all the limitations of the present invention except the hydrogel core being poly(vinyl alcohol) or poly(acrylonitrile) and that it would be obvious to one having ordinary skill in the art at the time the invention was made to use either of these materials ....

Again, Applicants respectfully disagree. As stated previously, Park provides a *crosslinked* hydrogel. This is very different than the *uncrosslinked* systems of the present invention. Use of the uncrosslinked polymers to afford the hydrogels provides the invention with a greater degree of swelling. Additionally, Park fails to teach or suggestion or provide any reason why one having ordinary skill in the art would select any polymers other than those specifically disclosed. Perhaps Park tried polyvinylalcohols and/or polyacrylonitriles and found they did not work....it is unknown. This is not simply a matter of design choice but of what works! Applicants have found certain *uncrosslinked* polymers work well; provide the appropriate strength to be used in a prosthetic that withstands incredible pressures and can swell to a degree larger than its initial state, while still retaining such strength!

Reconsideration and withdrawal of the rejection is respectfully requested.

Conclusion

This application now stands in allowable form and reconsideration and allowance is respectfully requested.

This response is being submitted on or before July 30, 2007 making this a timely response (as July 29<sup>th</sup> was a Sunday). Therefore, this response meets the requirements for expedited review. Consequently, expedited review is respectfully requested. It is believe that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief, which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

Respectfully submitted,

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Date:

July 30, 2007

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